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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/445,193 12/02/99 OHKAWA

S 2470USOP

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TAKEDA PHARMACEUTICALS NORTH AMERICA, IN
INTELLECTUAL PROPERTY DEPARTMENT
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EXAMINER

ROBINSON, B

ART UNIT

PAPER NUMBER

1625

DATE MAILED:

10/03/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/445,193

Applicant(s)

OHKAWA ET AL.

Examiner

Binta M. Robinson

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-15, 22-26, 28 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 24 is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-15, 22, 26 and 28 is/are rejected.
- 7) ☒ Claim(s) 25 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09445193.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Detailed Action

Upon review of applicant's amendment at paper no. 12, the 112, 1st paragraph rejection of claims 1-3, 5-15, and 22 for lack of description of the new subgenus is withdrawn and the 112, first paragraph rejection of claims 22, 25, 27, and 29 for lack of enablement for the method of treating all diseases related to neurodegeneration are withdrawn.

(old rejection)

1 The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 5-15 and 22 are rejected under 35 U.S.C. 112, first paragraph, for reasons of record at paper no. 8.

(new rejection)

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 26-28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, does not reasonably provide enablement for the method of treating all of the various diseases, many of which are unrelated. Alzheimer's Disease, which is mediated by serotonin, dopamine, and choline is unrelated to Parkinson's disease, which is a disease where the tremorine compound is diminished. There is currently no known treatment for amyotrophic lateral sclerosis. If Huntington's chorea is not detected in the fetal stage, it can't be treated. There is insufficient data in the specification showing how Huntington's chorea can be treated when this disease is often undetectable until the mid-30s, if not caught in the fetal stages. It is known that blood flow to tissues in diabetic neuropathy is impeded. The specification does not address how pharmaceutical treatments of diabetic neuropathy can be effective in light of the fact that blood flow to tissues is impeded. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The claims as recited are broader than the scope of enablement. The applicant does not provide

The applicant is referred to *In re Wands*, 858 f.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) which includes the incorporation of the 8 factors recited in *Ex parte* foreman 230 USPQ 546 (Bd. Of App. And Inter 1986).

Response to Applicant's remarks & Explanation of Rejections

112, 1st paragraph rejection (old rejection)

3. Applicant alleges that the specification provides enablement for all of the permutations and combinations of compounds of the formula in claim 1

Art Unit: 1625

where R1 and R2 come together to form a 3 to 8 member carbocyclic or heterocyclic ring, because of the existence of examples 30-33 on pages 991-102, where spiro compounds are represented. However, the claimed compounds of formula I are not limited where R1 and R2 form only spiro compounds, but claim the whole breadth of all possible permutations of 3 to 8 membered carbocyclic or heterocyclic rings. The applicant has not provided working examples for compounds where R1 and R2 come together to form rings other than spiro and there is no scientific data on examples 30-33 to show how these compounds in addition to all the permutations of compounds where R1 and R2 come together to form a 3 to 8 membered carbocyclic or heterocyclic ring, suppress amyloid toxicity. Spiro containing compounds of formula I would not be expected to have the same properties as compounds of formula I where R1 and R2 come together to form a pyridine ring for example. The disclosure does not satisfy the enablement requirement because it does not satisfy the 8 Wands factors. These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art 6) the amount of direction provided by the inventor 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In *re Wands*, 858 F. 2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Any necessary experimentation would be "undue"

112, 1st paragraph rejection (new rejection)

Art Unit: 1625

4. Claims 26 and 28 are rejected under 112, 1st paragraph, because the specification, does not reasonably provide enablement for the method of treating all of the various diseases, many of which are unrelated. A drug does not pharmaceutically act by treating various types of unrelated diseases caused by different etiologies. For instance, treating Alzheimer's disease does not mean you can treat Parkinson's disease. Additionally, there is currently, no treatment for amyotrophic lateral sclerosis.

Claim 24 appears to be allowable. Claim 25 is objected to because it is based on a rejected claim.

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Art Unit: 1625

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta M. Robinson whose telephone number is (703) 306-5337. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on (703)308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-7922 for regular communications and (703)308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-223.

Binta Robinson



September 28, 2001



ALAN L. ROTMAN
PRIMARY EXAMINER